X-Cell™
Wilson-Cook
Photodynamic Therapy Balloon with Fiber Optic Diffuser

Important Information
Please Review Prior to Use

PRODUCT DESCRIPTION

1. A non-sterile single-use 400 micron coated silica cylindrical fiber optic diffuser manufactured with a proximal SMA-type laser connector and a distal light-diffusing tip. It is designed to transmit and uniformly distribute light energy radially over the specified active length of the diffuser tip.
2. A non-sterile single-use centering balloon for intraluminal laser light delivery. The inflated balloon is designed to center the fiber optic in the esophagus. The treatment length is defined by the length of the transparent window in the balloon wall.

INTENDED USE

The X-Cell PDT Balloon with Fiber Optic Diffuser is designed for use in Photodynamic Therapy with PHOTOFRIN® (porfimer sodium) for injection for ablation of high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy.

The X-Cell Photodynamic Therapy Balloon with Fiber Optic Diffuser is designed for endoscopic positioning for delivery of laser light and should only be used with the Diomed® 630 PDT Laser Model T2USA, the Laserscope Series 600 KTP/532® Surgical Laser in combination with Laserscope Model 630 or Model 630 XP Dye Module or the Laserscope Series 600 KTP/YAG™ Surgical Laser in combination with Laserscope Model 630 or Model 630 XP Dye Module.

This device is supplied non-sterile and intended for single use only.

Instructions for use of the X-Cell Photodynamic Therapy Balloon with Fiber Optic Diffuser, PHOTOFRIN, and the laser manufacturer's instructions should be read carefully before use.

NOTES

Do not use this device for any purpose other than the stated intended use.

If the product package is open or damaged when received, do not use the device.

Wilson-Cook devices must be stored in a dry location, away from temperature extremes.

Refer to the PHOTOFRIN Package Insert for complete instructions concerning the drug.

Refer to the laser manufacturer's instructions for complete instructions concerning the laser.

CONTRAINDICATIONS

Contraindications include those specific to upper GI endoscopy.

Relative contraindications include, but are not limited to: uncooperative patient, recent myocardial infarction, cervical arthritis with fixed cervical spine.

For all other contraindications refer to the PHOTOFRIN Package Insert and the laser manufacturer's instructions.

POTENTIAL COMPLICATIONS

Potential complications associated with upper GI endoscopy include, but are not limited to: perforation, hemorrhage, aspiration, fever, infection, sepsis, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest.

For all other potential complications refer to the PHOTOFRIN Package Insert and the laser manufacturer's instructions.

PRECAUTIONS

This device contains glass fiber that may break if handled roughly or bent sharply. Do not clamp fiber directly.

Follow the laser manufacturer's instructions for setup and operation. Do not exceed maximum laser power setting (see PREPARATION FOR USE).

Assure that the laser light is not being transmitted when the diffuser is removed from the power meter.

Avoid inadvertent photoactivation of non-target tissue. Ensure that the laser light is not being transmitted when the diffuser is removed from the treatment site.

CAUTIONS

A thorough understanding of the technical principles, clinical applications and risks associated with upper GI endoscopy, Photodynamic Therapy, the Diomed 630 PDT Laser or the Laserscope Series 600 KTP/532 Surgical Laser in combination with Laserscope Model 630 or Model 630 XP Dye Module or the Laserscope Series 600 KTP/YAG Surgical Laser in combination with Laserscope Model 630 or Model 630 XP Dye Module, and the use of the X-Cell Photodynamic Therapy Balloon with Fiber Optic Diffuser is necessary before using this device. This device should be placed by or under the supervision of physicians who have been trained in the use of PHOTOFRIN in Photodynamic Therapy (PDT).

These instructions are applicable only to the X-Cell Photodynamic Therapy Balloon with Fiber Optic Diffuser used in conjunction with PHOTOFRIN and the Diomed 630 PDT Laser or the Laserscope Series 600 KTP/532 Surgical Laser in combination with Laserscope Model 630 or Model 630 XP Dye Module or the Laserscope Series 600 and KTP/YAG Surgical Laser in combination with Laserscope Model 630 or Model 630 XP Dye Module in photodynamic therapy.

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WARNINGS

Use of incompatible lasers that alter the required output characteristics of light for the photoactivation of PHOTOFRIN could result in incomplete treatment due to partial photoactivation of PHOTOFRIN, overtreatment due to overactivation of PHOTOFRIN, damage to surrounding normal tissue, and/or damage to the X-Cell Photodynamic Therapy Balloon with Fiber Optic Diffuser which could additionally create a hazard for medical personnel and/or the patient.

Always wear protective eyewear during laser light delivery. Avoid eye or skin exposure to direct or scattered radiation. Do not view the beam directly, even while wearing protective eyewear. Provide eye protection for patient in addition to all operating room staff.

EQUIPMENT REQUIRED

- X-Cell Photodynamic Therapy Balloon with Tuohy-Borst Adapter
- Fiber Optic Positioning Device
- Fiber Optic Diffuser (recommended sizes referenced in the following table)
- Manometer (not included)
- 260 cm Savary-Gilliard® Wire Guide (not included)
- Diomed 630 PDT Laser, Model T2USA

or

Laserscope Series 600 KTP/532 Surgical Laser in combination with Laserscope Model 630 or Model 630 XP Dye Module or the Laserscope Series 600 KTP/YAG Surgical Laser in combination with Laserscope Model 630 or Model 630 XP Dye Module

Table 1: Selection criteria for the X-Cell Photodynamic Therapy Balloon with Fiber Optic Diffuser

Treated Barrett's Mucosa Length (cm)	Fiber Optic Diffuser Size (cm)	Balloon Window Size (cm)
6 to 7	9	7
4 to 5	7	5
1 to 3	5	3

SYSTEM PREPARATION

Approved Laser Systems:

The following laser systems are compatible in PDT with the X-Cell Photodynamic Therapy Balloon with Fiber Optic Diffuser and PHOTOFRIN and are approved for delivery of a stable power output at a wavelength of 630 ±3 nm:

- Diomed 630 PDT Laser, Model T2USA
- Laserscope Series 600 KTP/532 Surgical Laser in combination with Laserscope Model 630 or Model 630 XP Dye Module or the Laserscope Series 600 KTP/YAG Surgical Laser in combination with Laserscope Model 630 or Model 630 XP Dye Module

Note: The input characteristics of the X-Cell Photodynamic Therapy Balloon with Fiber Optic Diffuser and the output characteristics of the approved laser systems have been tested to assure that they are optically matched to produce uniform light distribution from the diffuser as required for the photoactivation of PHOTOFRIN.

The use of the X-Cell Photodynamic Therapy Balloon with Fiber Optic Diffuser with unapproved lasers could alter the output characteristics of the fiber (see WARNINGS). Certain pulsed lasers with high peak powers are not compatible with the X-Cell Photodynamic Therapy Balloon with Fiber Optic Diffuser.

Laser Safety

Use protective eyewear specifically rated for laser operating over the range of 630 ±3 nm. Provide eye protection for patient in addition to all operation room staff (see WARNINGS). Comply with facility laser safety requirements.

Follow the laser manufacturer's operating manual for setup, operation and laser safety. Do not exceed maximum laser power setting without investigating the cause for the apparent high power loss (see PREPARATION FOR USE).

Dosimetry:

Photoactivation of PHOTOFRIN is controlled by the total light dose delivered. In the treatment of Barrett's esophagus, the objective is to expose and treat all areas of HGD and the entire length of Barrett's esophagus. A maximum of 7 cm of Barrett's mucosa is treated at the first light session using an appropriate size centering balloon and fiber optic diffuser. Whenever possible, the segment selected for the first light application should contain all the areas of HGD. Also, whenever possible, the BE segment selected for the first light application should include normal tissue margin of 5 mm at the proximal and distal ends.

Nodules should be pretreated prior to use of the X-Cell Photodynamic Therapy Balloon with Fiber Optic Diffuser. Refer to the PHOTOFRIN Package Insert, the laser manufacturer's instructions, and the OPTIGUIDE™ Fiber Optic Instructions for Use.

A light dose of 130 J/cm of diffuser length should be delivered using the centering balloon. Based on preclinical studies, acceptable light intensities for the balloon/diffuser combinations range from 175 to 270 mW/cm.

For the X-Cell Photodynamic Therapy Balloon with Fiber Optic Diffuser, the following specific light dosimetry equation applies:

$$\text{Treatment time (Seconds)} = \frac{\text{Light Dose (J/cm)} \times \text{Diffuser Length (cm)}}{\text{Power output from Diffuser (W)}}$$

See reverse side for Table 2.

X-Cell Photodynamic Therapy Balloon with Fiber Optic Diffuser Selection:

The fiber and balloon components of the X-Cell Photodynamic Therapy Balloon with Fiber Optic Diffuser are available in several sizes. The length of the balloon/diffuser should be selected to minimize patient treatment time. It is dictated by the length of the High Grade Dysplasia.

An appropriate balloon/diffuser length should be selected to avoid exposure of non-malignant tissue to light and to minimize overlapping of previously treated malignant tissue. Overlapping could result in unintended light overdose.

Patients can receive an additional course of PDT (administered at least 3 months apart) to a previously treated segment or to a new segment if the initial Barrett's segment was more than 7 cm in length. Both residual and additional segments can be treated in the same light session provided that the total length of the segments treated with the balloon/diffuser combination is not greater that 7 cm.

In case of a previously treated esophageal segment, if it has not sufficiently healed and/or histological assessment of biopsies is not clear, the subsequent course of PDT can be delayed for an additional one or two months.

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PREPARATION FOR USE

1. Prepare the Diomed 630 PDT Laser or the Laserscope Series 800 KTP/532 or KTP/YAG Surgical Laser for delivery of 630 ±3 nm light as indicated in the laser manufacturer's instructions. Select minimal power setting (approximately 10 mW).
2. Endoscopically locate and mark the upper and lower margins of the treatment segment relative to the dental margin (incisors), then select the appropriate size balloon treatment window. **Caution:** Accurate marking of the treatment segment is essential for selection of the appropriate balloon size and placement of the balloon treatment window.
3. Upon removing the device from the package, visually inspect with particular attention to kinks, bends, or breaks. If an abnormality is detected that would prohibit proper working condition, do not use. Please notify Wilson-Cook for return authorization.
4. Gently unclip the SMA connector of the fiber optic diffuser. Remove the fiber optic diffuser from the tray by gently grasping all the fiber coils and pulling the entire fiber optic diffuser from the tray. Inspect for visible signs of damage with particular attention to kinks, bends, or breaks. If an abnormality is detected that would prohibit proper working condition, do not use. Please notify Wilson-Cook for return authorization.
5. Remove protective cap from the SMA connector without touching the polished end of the SMA. Check the surface of the SMA connector for contamination. If contamination is present, gently clean with a single wipe of lens tissue soaked in 70% IPA. If the SMA connector cannot be cleaned, the fiber must not be used.
6. Seat the SMA connector into the laser fiber port and secure by turning the SMA nut until it is finger-tight. Do not over-tighten.
7. Turn on the aiming beam of the laser and examine the fiber optic looking for unusually bright spots or severe kinks. Do not use if there are any signs of damage or breakage.
8. Completely insert the diffuser tip of the treatment fiber into the power meter and measure the fiber optic power output.
9. Adjust the laser power setting to obtain the specified power output for the treatment fiber model. Refer to Table 2.

INSTRUCTIONS FOR USE

1. Insert the fiber optic positioning device into the distal end of the balloon catheter.
2. Insert the fiber optic diffuser into the Tuohy-Borst adapter on the proximal end of the balloon catheter and advance until the diffuser stops against the centering pin of the positioning device.
3. With the aiming beam ON, visually verify that the diffuser is centered through the treatment window, then tighten the compression fitting of the Tuohy-Borst adapter to set the appropriate distance for the fiber optic diffuser.
4. Remove the fiber optic diffuser and entire Tuohy-Borst adapter assembly from the balloon catheter, being careful not to dislodge the compression fitting from the fiber optic diffuser.
5. Remove the fiber optic positioning device from the distal end of the balloon catheter. The balloon catheter is now ready for placement.
6. Place the tip of the endoscope into the stomach.
7. Introduce a 250 cm Savary-Gilliard wire guide, floppy tip first, into the accessory channel of the endoscope and advance in short increments until it is endoscopically visualized and positioned well into the stomach.
8. Remove the endoscope, leaving the wire guide in place. **Note:** Fluoroscopy is recommended to reconfirm placement of the wire guide.
9. Introduce the PDT balloon catheter over the pre-positioned wire guide, and advance into the stomach.
10. Introduce a standard pediatric endoscope and position the tip at the proximal end of the treatment segment. Withdraw the endoscope 3 cm to allow proper positioning of the balloon treatment window. Pull back the balloon and adjust so the yellow marker on the catheter is just visible through the endoscope. This ensures that the balloon window is placed directly over the intended treatment segment. **Note:** Position the proximal end of the balloon treatment window 0.5 cm above the proximal end of the treatment segment to allow for balloon and esophageal position changes during treatment.
11. Remove wire guide.
12. Attach the manometer extension line to the inflation hub on the balloon catheter and inflate the balloon to a pressure of 20-30 mm Hg. **Warning:** Do not inflate the balloon to a pressure higher than 30 mm Hg.
13. Insert the fiber optic diffuser with attached Tuohy-Borst adapter into the fiber optic hub on the balloon catheter. Advance the diffuser into the hub until the Tuohy-Borst adapter seats into the Luer lock fitting on the balloon catheter, then tighten. The diffuser should now be centered within the treatment window of the balloon. **Note:** If the treatment fiber is disconnected and reconnected to the laser, confirm and/or adjust the power level.
14. Attach a syringe containing 10 cc of saline to the side port of the Tuohy-Borst adapter, then flush the lumen of the balloon to remove any secretions. Keep the syringe attached to the port. Atropine sulfate (0.4 mg) and glucagon (1.0 mg) may be administered if secretion or esophageal motility are excessive. **Note:** Endoscopically verify the appropriate position of the balloon. **Caution:** Before proceeding with PDT treatment, ensure that the correct diffuser length is entered into the PDT laser display of the Diomed 630 PDT Laser. For the Laserscope Series 800 KTP/532 and KTP/YAG Surgical Lasers, ensure that the correct power is entered into the laser. **Caution:** Proper inflation pressure of the balloon should be checked using manometry prior to light application and continually during treatment procedure.
15. Begin delivery of laser light and expose the treatment site for the appropriate time. **Caution:** Do not move the balloon/diffuser during the exposure period. **Caution:** Do not exceed 270 mW/cm at 630 nm.
16. Stop laser light delivery.
17. When PDT treatment is complete, disconnect the manometer and extension line from the inflation hub to deflate the PDT balloon. Disconnect the treatment fiber from the laser. Carefully remove the deflated balloon and fiber, then dispose of the PDT balloon and diffuser per institutional guidelines for biohazardous medical waste.
18. Treatment area may be endoscopically viewed, if desired. Upon completion of the procedure, remove the endoscope.

Table 2: Fiber Optic Power Outputs and Treatment Times Required to Deliver 130 J/cm of Diffuser Length using the X-Cel Photodynamic Therapy Balloon with Fiber Optic Diffuser[a]

Treated Barrett's Mucosa Length (cm)	Fiber Optic Diffuser Length (cm)	Balloon Window Size (cm)	Light Intensity	Fluence (mW/cm)	Required power output from diffuser[b] (W)	Treatment time (min:sec)
1 to 3	5	3	high	270	1.35	8:00
4 to 5	7	5	high	270	1.895	8:00
6 to 7	9	7	low	200	1.80	10:50
			high[c]	270	2.44	8:00

[a] Whenever possible, the Barrett's esophagus (BE) segment selected for treatment should include normal tissue margins of approximately 5 millimeters at the proximal and distal ends.

[b] As measured by immersing the diffuser into the cuvet in the power meter and slowly increasing the laser power.

[c] High light intensity applies only to the Laserscope Series 800 KTP/532 and KTP/YAG Surgical Lasers

Note: No more than 1.5 times the required diffuser output should be needed from the laser. If more than this is required, the system is to be checked.

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GI Endoscopy

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